(Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655 (c)))

Issued in Jamaica, N.Y., on July 10, 1974.

JAMES BISPO,
Deputy Director, Eastern Region.

1. Amend § 71.171 of Part 71, Federal Aviation Regulations so as to alter the description of the Lewisburg, W. Va. Control Zone by deleting the last sentence and by substituting in lieu thereof: "This Control Zone is effective during the specific days and times established in advance by a Notice to Airmen. The effective times will thereafter be published in the Airman's Information Manual."

[FR Doc.74-17080 Filed 7-25-74;8:45 am]

[Airspace Docket No. 74-SW-34]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Control Zone

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to alter the Tulsa, Okla. (Riverside Airport), control zone.

On May 1, 1974, FR Doc. 74-9902 was published in the FEDERAL REGISTER (39 FR 15099) altering the Tulsa, Okla. (Riverside Airport), control zone effective 0901 Gmt, July 18, 1974. Subsequent to publication of this document, it was determined to retain the existing VOR/DME RWY 36L instrument approach procedure to the Riverside Airport. This requires retention of the existing southwest extension of the control zone to contain the aircraft within controlled airspace.

Also, subsequent to publication of Document 74-9902, the name of the Riverside TVOR was changed to Glenpool TVOR, and commissioning will be delayed until October 10, 1974.

Since this action is minor in nature and one upon which the public would not have particular reason to comment, notice and public procedure thereon are unnecessary.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended effective 0901 g.m.t., October 10, 1974, as hereinafter set forth.

In § 71.171 (39 FR 354), the Tulsa, Okla. (Riverside Airport), control zone is amended to read:

TULSA, OKLA. (RIVERSIDE AIRPORT)

Within a 5-mile radius of Riverside Airport (latitude 36°02'19" N., longitude 95°59'00" W.), within 2 miles each side of the Glenpool TVOR 349° radial extending from the 5-mile radius zone to the TVOR and within 2.5 miles each side of the Tulsa VORTAC 223° radial extending from the 5-mile radius zone to 21 miles southwest of the VORTAC. This control zone is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airman's Information Manual.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Fort Worth, Tex., on July 11, 1974.

ALBERT H. THURBURN,
Acting Director, Southwest Region.

[FR Doc.74-17085 Filed 7-25-74;8:45 am]

[Airspace Docket No. 74-SW-27]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Designation of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to designate a 700-foot transition area at Eagle Pass, Tex.

On June 11, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 20500) stating the Federal Aviation Administration proposed to designate the Eagle Pass, Tex., transition area.

Interested persons were afforded an opportunity to participate in the rulemaking through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., October 10, 1974, as hereinafter set forth.

In § 71.181 (39 FR 440), the following transition area is added:

EAGLE PASS, TEX.

That airspace extending upward from 700 feet above the surface within a 5-mile radius of the Eagle Pass Municipal Airport (latitude 28°42'00" N., longitude 100°28'45" W.) and within 3 miles each side of the 089° bearing from the Eagle Pass RBN (latitude 28°42'20" N., longitude 100°29'10" W.) extending from the 5-mile radius area to 8 miles east of the Eagle Pass RBN excluding the portion outside the United States.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c))

Issued in Fort Worth, Tex., on July 18, 1974.

JOHN A. DUFFICY,
Acting Director, Southwest Region.

[FR Doc.74-17082 Filed 7-25-74;8:45 am]

[Airspace Docket No 74-SW-30]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to alter the 700-foot transition area at Intracoastal City, La.

On June 11, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 20500) stating the Federal Aviation Administration proposed to alter the Intracostal City, La., transition area.

Interested persons were afforded an opportunity to participate in the rulemaking through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., October 10, 1974, as hereinafter set forth.

In § 71.181 (39 FR 440), the Intracoastal City, La., transition area is amended as follows:

INTRACOASTAL CITY, LA.

That airspace extending upward from 700 feet above the surface within 2 miles each side of the White Lake, La., VORTAC 062° radial extending from 9 miles NE of the VORTAC to 13 miles NE of the VORTAC and within 3.5 miles each side of the White Lake VORTAC 065° radial extending from 17 miles NE of the VORTAC to 23 miles NE of the VORTAC.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Issued in Fort Worth, Tex., on July 18, 1974.

JOHN A. DUFFICY,
Acting Director, Southwest Region.

[FR Doc. 74-17084 Filed 7-25-74;8:45 am]

[Airspace Docket No. 74-SW-24]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Designation of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to designate a 700-foot transition area at Leeville, La.

On May 30, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 18800) stating the Federal Aviation Administration proposed to designate the Leeville, La., transition area.

Interested persons were afforded an opportunity to participate in the rulemaking through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., September 12, 1974, as hereinafter set forth.

In § 71.181 (39 FR 440), the following transition area is added:

LEEVILLE, LA.

That airspace extending upward from 700 feet above the surface within 3.5 miles either side of the Leeville, La., VORTAC 275° radial extending from the VORTAC to 14 miles west of the VORTAC.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Issued in Fort Worth, Tex., on July 11, 1974.

ALBERT H. THURBURN,
Acting Director, Southwest Region.

[FR Doc.74-17087 Filed 7-25-74;8:45 am]

[Airspace Docket No. 74-SW-23]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to alter the McAllen, Tex., transition area.

On May 30, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 18801) stating the Federal Aviation Administration proposed to alter the transition area at McAllen, Tex.

Interested persons were afforded an opportunity to participate in the rulemaking through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., September 12, 1974, as hereinafter set forth.

In § 71.181 (39 FR 440), the McAllen, Tex., transition area is amended to read:

MCALLEN, TEX.

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Miller International Airport (latitude 26°10'40" N., longitude 98°14'25" W.); within 3.5 miles each side of the McAllen VOR 095° radial extending from the 5-mile radius area to 11.5 miles east of the VOR; within 4 miles south and 5 miles north of the McAllen VOR 321° radial extending from the 5-mile radius area to 18.5 miles northwest of the McAllen VOR; and within 2 miles each side of the localizer (latitude 26°09'59" N., longitude 98°13'53" W.) back course 141° radial extending from the 5-mile radius area to 5.5 miles southeast of the localizer, excluding the portion outside the United States.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Issued in Fort Worth, Tex., on July 11, 1974.

A. H. THURBURN,
Acting Director,
Southwest Region.

[FR Doc.74-17086 Filed 7-25-74;8:45 am]

[Airspace Docket No. 74-SW-28]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Designation of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to designate a 700-foot transition area at Morgan City, La.

On June 11, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 20501) stating the Federal Aviation Administration proposed to designate the Morgan City, La., transition area.

Interested persons were afforded an opportunity to participate in the rulemaking through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., October 10, 1974, as hereinafter set forth.

In § 71.181 (39 FR 440), the following transition area is added:

MORGAN CITY, LA.

That airspace extending upward from 700 feet above the surface within 3.5 miles each side of the Tibby, La., VORTAC 281° radial extending from 11.5 miles west of the VORTAC to 23 miles west of the VORTAC. (Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Issued in Fort Worth, Tex., on July 18, 1974.

JOHN A. DUFFICY,
Acting Director,
Southwest Region.

[FR Doc.74-17083 Filed 7-25-74;8:45 am]

[Airspace Docket No. 74-SW-29]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Designation of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to designate a 700-foot transition area at Sabine Pass, Tex.

On June 11, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 20501) stating the Federal Aviation Administration proposed to designate the Sabine Pass, Tex., transition area.

Interested persons were afforded an opportunity to participate in the rulemaking through submission of comments. All comments received were favorable.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., October 10, 1974, as hereinafter set forth.

In § 71.181 (39 FR 440), the following transition area is added:

SABINE PASS, TEX.

That airspace extending upward from 700 feet above the surface within 3.5 miles each side of the Sabine Pass, Tex., VORTAC 093° radial extending from the VORTAC to 17.5 miles east of the VORTAC.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Fort Worth, Tex., on July 18, 1974.

JOHN A. DUFFICY,
Acting Director,
Southwest Region.

[FR Doc.74-17081 Filed 7-25-74;8:45 am]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCES ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

PART 1512—REQUIREMENTS FOR BICYCLES

Banning of Hazardous Bicycles; Establishment of Safety Requirements

Correction

In FR Doc. 74-15315 appearing at page 26100 in the issue of Tuesday, July 16, 1974, the following changes should be made:

1. In § 1512.5(e)(3), the figure "0.56 (22 in.)" in the second line should read "0.56 m (22 in.)".

2. In § 1512.18(b)(2), the figure "7.8 mm 5/16 in.)" in the second line should read "7.8 mm (5/16 in.)".

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart D—Food Additives Permitted in Food for Human Consumption

ASPARTAME

In the FEDERAL REGISTER of March 5, 1973 (38 FR 5921), notice was given that a petition (FAP 3A2885) had been filed by G. D. Searle & Co., Box 5110, Chicago, IL 60680, proposing the issuance of a food additive regulation to provide for the safe use of aspartame (L-aspartyl-L-phenylalanine methyl ester) in foods as a nutritive substance with intense sweetness and with flavor-enhancing properties.

Subsequently, the petitioner amended the petition by proposing additionally the safe use of L-leucine, for technological purposes, in tablets containing aspartame.

The Commissioner of Food and Drugs has evaluated the data in the petition, and other relevant material, and concludes that the food additive regulations should be amended, as set forth below, to provide for the safe use of the petitioned additives. Because the appearance of this new sweetener is expected to elicit considerable public interest, a discussion of the new regulation is set forth in this preamble.

1. Aspartame is the methyl ester of a synthetic dipeptide of two amino acids, i.e., L-aspartic acid and L-phenylalanine. The chemical terminology for designation of aspartame has been revised slightly in order to be consistent with the terminology employed by Chemical

Abstracts Service: 1-methyl *N*-L-α-aspartyl-L-phenylalanine

2. Aspartame is intensely sweet—about 180 times as sweet as sugar. When consumed, it is metabolized as a protein, unlike sugar which is metabolized as carbohydrate. Like sugar or protein, aspartame provides approximately 4 calories per gram; however, because of its greater sweetness, if aspartame is employed as a sweetener in place of sugar it will provide only about 1/180th of the calories that would be provided by the use of a quantity of sugar yielding equivalent sweetness. Aspartame differs from saccharin, which may be used as a sweetening agent in certain foods pursuant to § 121.4001 (21 CFR 121.4001), in that saccharin provides no calories. However, because of its intense sweetness, the amount of aspartame needed to sweeten food satisfactorily may often be so small that its caloric contribution will be minute and insignificant.

3. Asparatame cannot be substituted for sugar without restriction. Prolonged cooking temperatures (such as, for example, those encountered in frying and baking) can cause significant breakdown of aspartame to diketopiperazine, with a consequent loss of sweetness. The order below does not approve any use of aspartame which would pose any prospect of appreciable breakdown to diketopiperazine.

4. The Commissioner approves the following uses of aspartame as a sweetener:

(a) Use in dry, free-flowing sugar substitutes for table use (not to include use in cooking) in package units not to exceed the sweetening equivalence of 2 teaspoonfuls of sugar.

(b) Use in sugar substitute tablets for sweetening hot beverages, including coffee and tea.

(c) Use in cold breakfast cereals.

(d) Use in chewing gum.

(e) Use in dry bases for: beverages, instant coffee and tea, gelatins, puddings, fillings, and dairy product analog toppings.

5. The Commissioner also approves use of aspartame as a flavor enhancer in chewing gum.

6. The Commissioner concludes that aspartame is safe for the above listed uses, under the conditions set forth in the regulation. A copy of all of the extensive research data on which this safety judgment is based has been placed on file, available for public inspection, in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852. Of principal significance, the petitioner submitted 2-year feeding studies with aspartame in rats and dogs and a lifetime feeding study in in-utero exposed rats. These chronic feeding studies provide sufficient support for the long term safety of the uses of aspartame permitted by the food additive regulation. These long term feeding studies, evaluated conservatively, reveal a "no effect" level for aspartame at least as high as 2 grams per kilogram of body weight. Employing a 100-fold safety factor, and applying this figure to the average 60-kilogram man, an acceptable intake level of at least 1.2 grams of aspartame per day results. A daily diet including the foods which may be sweetened with aspartame in accordance with this order might lead to a probable maximum ingestion of 1.3–1.7 grams of aspartame per day. Considering the conservativeness of the "no effect" level derived from the animal tests and the 100-fold safety factor employed in relating the tests to man, the Commissioner concludes that the uses approved by this regulation constitute an acceptable daily intake of aspartame with an ample margin of safety. Research data involving humans confirm safety for at least this level of consumption.

7. Diketopiperazine (5 benzyl-3, 6-dioxo-2-piperazineacetic acid) is the breakdown derivative of aspartame, routinely present in the sweetener at levels up to about 1 percent of the aspartame. At such levels the safety of diketopiperazine is shown by the safety studies on aspartame mentioned above. Additional data on diketopiperazine itself support a judgment that the substance is safe in aspartame, when used in accordance with the regulation, up to a level of at least 2 percent, and accordingly, the final order authorizes use of aspartame which contains no more than 2 percent diketopiperazine. None of the uses of aspartame authorized by the order below would be likely to result in significant breakdown of aspartame to higher levels of diketopiperazine. The Commissioner is not aware of any studies which indicate any toxicological problems with diketopiperazine, even at higher levels; however, he advises that any future requests for uses of aspartame which involve a prospect at significant breakdown to higher levels of diketopiperazine will be required, prior to approval, to demonstrate affirmatively that the anticipated higher levels are safe. The Commissioner understands that long term feeding studies of diketopiperazine are in progress.

8. In the digestive tract, aspartame is hydrolyzed to L-aspartic acid and L-phenylalanine, two amino acids which occur naturally in food protein. Both of these amino acids have previously been approved as safe for addition to food so as to improve the biological quality of protein, under §§ 121.101 and 121.1002 (21 CFR 121.101 and 121.1002). The amounts of L-aspartic acid and L-phenylalanine which would enter the diet from the uses permitted by this order are nutritionally insignificant and too small to pose any risk of amino acid imbalance.

9. The regulation also permits the use of L-leucine as a lubricant in the manufacture of tablets containing aspartame for sweetening hot beverages, at a level not to exceed 3.5 percent of the weight of the tablet. L-leucine, like L-aspartic acid and L-phenylalanine, is an amino acid which occurs naturally in food protein and which has been approved as safe for addition to food so as to improve the biological quality of protein, in §§ 121.101 and 121.1002. The amount of L-leucine which would enter the diet from the use permitted by this order is nutritionally insignificant and too small to pose any risk of amino acid imbalance.

10. The Commissioner recognizes that L-phenylalanine intake must be restricted by persons with phenylketonuria (PKU), an inborn error in metabolism. Since L-phenylalanine is a naturally occurring amino acid found in many foods, a person with PKU is already accustomed to checking all of his dietary intake so as to minimize consumption of the substance. The Commissioner has determined that in order to assure the safe use of aspartame in food, all finished foods containing aspartame must include an appropriate warning to phenylketonurics that the food contains L-phenylalanine. This order provides in detail the requirements for such warnings. The petitioner submitted studies showing that the uses of aspartame authorized by the regulation will not result in elevation of phenylalanine blood levels; nevertheless, in the judgment of the Commissioner, the aforementioned warning is necessary in the interest of safety.

11. High levels (3 and 4 grams per kilogram of body weight) of aspartame, when fed to infant monkeys, have been reported by one investigator to be associated with toxic manifestations. The same results were reported by the investigator when L-phenylalanine was fed at similarly high levels. These test levels are far in excess of the ingestion levels of aspartame and its L-phenylalanine component which could be expected to result from this regulation, as discussed in paragraphs 6 and 8 of this preamble.) In any event, none of the uses approved by the order would be likely to result in consumption of significant levels of aspartame by human infants. The long term feeding studies cited in paragraph 6 of this preamble demonstrate the safety of aspartame under the conditions of use approved by the order.

12. The Commissioner is aware of data indicating that high oral intubation dosages and subcutaneous injections of monosodium glutamate may have a toxic effect on newborn animals, and he is aware that L-aspartic acid (treated in paragraph 8 of this preamble) has been reported to act similarly to monosodium glutamate. However, the newborn infant animal is a hypersensitive subject, and in any event subcutaneous injection of a compound is an inappropriate method of investigating its safety as a food additive and the oral intubation dosages of monosodium glutamate involved, i.e., over 1 gram per kilogram of body weight in the newborn animal, were greatly in excess of the levels of aspartic acid which can be expected to result from the uses of aspartame permitted by the regulation, i.e., 0.013 milligram per kilogram of body weight. Furthermore, none of the uses of aspartame approved by this order involves the feeding of newborn infants. A copy of the *Scientific Literature Review on Glutamates*, February 8, 1974, which reviews the scientific literature regarding

monosodium glutamate, is on public file in the office of the Hearing Clerk.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 2.120), Part 121 is amended by adding a new section to Subpart D as follows:

§ 121.1258 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent or for an authorized technological purpose in foods for which standards of identity established under section 401 of the act do not preclude such use under the following conditions:

(a) Aspartame is the chemical

1-methyl N-L-α-aspartyl-L-phenylalanine ($C_{14}H_{18}N_2O_5$).

(b) The additive meets the following specifications:

(1) Not less than 98.0 percent and not more than the equivalent of 102.0 percent $C_{14}H_{18}N_2O_5$ (aspartame), calculated on the dried basis (4 hours at 105° C), as determined by the following analytical method.

APPARATUS

Titration vessel. Glass beaker or flask, 150 milliliters.

Buret. 50 milliliters with 0.1-milliliter gradations, equipped with tetrafluoroethylene polymer stopcock.

Aluminum foil.

Optional equipment. Magnetic stirrer and tetrafluoroethylene polymer-coated magnetic bar.

REAGENTS

Lithium metal.

Methyl alcohol. Absolute, A.C.S. reagent grade.

Benzene. Anhydrous, A.C.S. reagent grade.

Thymol blue (thymolsulfonephthalein). A.C.S. reagent grade.

Ethyl alcohol. 95 percent.

Benzoic acid. A.C.S. reagent grade, of specified purity dried at 80° C.

N,N-Dimethylformamide. A.C.S. reagent grade.

Lithium methoxide solution. 0.1 normal; dissolve 600 milligrams of lithium metal in 150 milliliters of absolute methyl alcohol and 850 milliliters of benzene. Filter the solution if cloudy.

Thymol blue solution. Dissolve 100 milligrams of thymol blue in 100 milliliters of 95 percent ethyl alcohol. Filter if necessary.

PROCEDURE

General instructions. Perform in triplicate both the standardization of the lithium methoxide solution and the titration of the sample. Perform one titration of the solvent blank, i.e., *N,N*-dimethylformamide. Cover the titration vessel with aluminum foil while dissolving the samples and throughout the titration to decrease carbon dioxide absorption.

Titration of solvent blank. Add 35 milliliters of *N,N*-dimethylformamide to the titration vessel. Add 5 drops of the thymol blue solution and titrate the mixture with lithium methoxide solution to an end point indicated by a color change from yellow to blue.

Determination of normality of the lithium methoxide solution. Place a weighed sample of benzoic acid (approximately 80 milligrams) in the titration vessel, add 35 milliliters of *N,N*-dimethylformamide and dissolve the sample. Add 5 drops of thymol blue solution to the dissolved sample and titrate with the lithium methoxide solution to an end point indicated by a color change from yellow to blue.

Titration of the aspartame sample. Place a weighed sample of aspartame (approximately 150 milligrams dried at 105° C for 4 hours and stored in a desiccator) in the titration vessel, add 35 milliliters of *N,N*,-dimethylformamide and dissolve the sample. Add 5 drops of thymol blue solution to the dissolved sample and titrate with the lithium methoxide solution to an end point indicated by a color change from yellow to blue.

CALCULATIONS

$$N = \frac{J}{(122.12)\ (S-B)}$$

$$\text{Percent aspartame in sample} = \frac{(294.3)\ (A-B)\ (N)}{K} \times 100$$

Where:

N = Accurate normality of the lithium methoxide solution.

S = Milliliters of lithium methoxide solution required to titrate the benzoic acid.

A = Milliliters of lithium methoxide solution required to titrate the aspartame sample.

B = Milliliters of lithium methoxide solution required to titrate the solvent blank.

J = Milligrams of benzoic acid standard.

K = Milligrams of aspartame sample.

(2) Specific rotation, $[\alpha]D^{30}$°, shall be between +12.5° and +17.5°, calculated on the dried basis (4 hours at 105° C) in accordance with the test for optical rotation described in the "Food Chemicals Codex," 2nd Ed. (1972),[1] page 939. Weigh accurately about 4 grams of sample and dissolve it in sufficient 15*N* formic acid to make exactly 100 milliliters of solution, and complete the determination of the rotation in a 100-millimeter tube within 30 minutes after preparing the solution.

(3) 5-Benzyl-3,6-dioxo-2-piperazineacetic acid (diketopiperazine) not to exceed 2.0 percent as determined by the following analytical method:

APPARATUS

Gas chromatograph. With hydrogren flame ionization detector and designed for handling glass columns with oncolumn injection (Micro-Tek 220 or equivalent). Chromotograph conditions should be optimized to obtain maximum resolution for the specific instrument used. To preclude buildup of silicon oxide, clean the detector with acetone frequently. Approximate operating conditions are:

Column temperature: 200° C.

Detector temperature: 275° C.

Inlet temperature: 200° C.

Carrier gas (helium) flow rate: 75 milliliters per minute.

Hydrogen and air flow to burner: Optimize to give maximum sensitivity.

Sample size: 3 microliters.

Elution time: 7–9 minutes.

Recorder: 1 millivolt full scale (for the Micro-Tek 220, the attenuation is 16x10).

Chromatograph column: 6 feet x 4 millimeters I.D. glass column packed with OV–1 on 80–100 mesh Supelcoport (Supelco, Inc., or equivalent). Condition the column overnight at 250° C before readjustment and equilibration to the operation conditions.

Oven. Capable of maintaining 80±1° C for 30 minutes.

Glass manifold. Suitable for evaporating samples to dryness over steam bath; the apparatus may have an optional gas flow over the sample to enhance the rate of solvent evaporation.

Vials. 2-dram size with tetrafluoroethylene polymer-lined cap.

REAGENTS

N,N-Dimethylformamide. A.C.S. reagent grade.

N,O-Bis(trimethylsilyl) acetamide.

Silylation reagent. Dilute by volume three parts *N,O*-bis(trimethylsilyl) acetamide with two parts *N,N*-dimethylformamide. Prepare fresh before use.

Methyl alcohol. Anhydrous, A.C.S. reagent grade.

5-Benzyl-3,6-dioxo-2-piperazineacetic acid. Specifications: Purity, not less than 99 percent; minimum melting point, 243° C; specific rotation of a 1 percent solution (in acetic acid), between −9° and −11°; total impurities determined by thin layer chromatography, less than 0.5 percent; impurities determined by gas chromatography, less than 1 percent for any single impurity. A sample of the reagent and test procedures for verification of specifications may be obtained from Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave., NW., Washington, DC 20418.

PROCEDURE

Preparation of the standard. Place a weighed sample of 5-benzyl-3,6-dioxo-2-piperazineacetic acid (25 milligrams) into a 50-milliliter volumetric flask. Add methyl alcohol to dissolve the solid standard and dilute to volume. Dilute a 10-milliliter portion of the above solution to 50 milliliters with methyl alcohol in another 50-milliliter volumetric flask. The concentration of this standard solution is 0.1 milligram per milliliter. Pipet 2 milliliters of the standard solution into a 2-dram vial and evaporate the solvent to dryness. Add 1 milliliter of the silylation reagent to the dried sample, cap the vial tightly, shake and place in an 80° C oven for 30 minutes. Remove from oven, shake vial 15 seconds and cool to room temperature. Inject 3 microliters of this solution into the gas chromatograph and measure the peak height. The standard should be injected either immediately before or after each sample for proper quantification.

Preparation of the aspartame sample. Place a weighed sample of aspartame (approximately 10 milligrams) into a 2-dram vial. Add 1 milliliter of silylation reagent to the vial, cap tightly, shake and place in an 80° C oven for 30 minutes. Remove from oven, shake vial 15 seconds and cool to room temperature. Inject 3 microliters of this solution into the gas chromotograph and measure the subject compound peak height.

[1] Copies may be obtained from: National Academy of Sciences, 2101 Constitution Ave., NW., Washington, DC 20037.

CALCULATION

$$\text{Milligrams of 5-benzyl-3,6-dioxo-2-piperazineacetic acid in aspartame} = \frac{\text{peak height of aspartame sample}}{\text{peak height of standard sample}} \times 0.2$$

$$\text{Percent 5-benzyl-3,6-dioxo-2-piperazineacetic acid in aspartame} = \frac{\text{milligrams of subject compound in aspartame}}{\text{milligrams of aspartame sample}} \times 100.$$

(c) The additive may be used as a sweetener in the following foods:

(1) Dry, free-flowing sugar substitutes for table use (not to include use in cooking) in package units not to exceed the sweetening equivalent of 2 teaspoonfuls of sugar.

(2) Sugar substitute tablets for sweetening hot beverages, including coffee and tea. L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(3) Cold breakfasts cereals.

(4) Chewing gum.

(5) Dry bases for:

(i) Beverages.

(ii) Instant coffee and tea.

(iii) Gelatins, puddings, and fillings.

(iv) Dairy product analog toppings.

(d) The additive may be used as a flavor enhancer in chewing gum.

(e) To assure safe use of the additive, in addition to the other information required by the act:

(1) The principal display panel of any intermediate mix of the additive for manufacturing purposes shall bear a statement of the concentration of the additive contained therein;

(2) The label of any food containing the additive shall bear, either on the principal display panel or on the information panel, the following statement: PHENYLKETONURICS: CONTAINS PHENYLALANINE

The statement shall appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) When the additive is used in a sugar substitute for table use, its label shall bear instructions not to use in cooking or baking.

(f) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with Part 125 of this chapter.

Any person who will be adversely affected by the foregoing order may at any time on or before August 26, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective on July 26, 1974.

(Sec. 409(c)(1), 72 Stat. 1786; (21 U.S.C. 348(c)(1).))

Dated: July 22, 1974.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

Note: Incorporation by reference approved by the Director of the Federal Register July 10, 1973.

[FR Doc.74-17093 Filed 7-24-74;8:45 am]

SUBCHAPTER C—DRUGS

PART 146e—CERTIFICATION OF BACITRACIN AND BACITRACIN-CONTAINING DRUGS FOR VETERINARY USE; TESTS AND METHODS OF ASSAY

Correction

In FR Doc. 74-12379 appearing at page 18771 of the issue for Thursday, May 30, 1974, on page 18788 the heading of Part 146e is incomplete, and should read as set forth above.

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 452—MACROLIDE ANTIBIOTIC DRUGS

Erythromycin Ethylcarbonate Monographs Revocation

In a notice of proposed rulemaking published in the FEDERAL REGISTER of February 28, 1974 (39 FR 7801), the Commissioner of Food and Drugs proposed that the antibiotic drug regulations be amended by revoking the monographs providing for certification of erythromycin ethylcarbonate since no requests for certification of the antibiotic drug have been received since 1967. Interested persons were invited to submit their comments in response to the proposal within 60 days. No comments were received. Subsequently, antibiotic drug regulations were recodified into a new Subchapter D—Drugs for Human Use, published in the FEDERAL REGISTER of May 30, 1974 (39 FR 18922). Accordingly the Commissioner concludes that the antibiotic drug regulations should be amended as set forth below.

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357) and under authority delegated to the Commissioner (21 CFR 2.120), Part 452 (which includes the former Part 148e) is amended by revoking § 452.20 (formerly 148e.2) *Erythromycin ethylcarbonate*, § 452.120a (formerly 148e.11) *Erythromycin ethylcarbonate for oral suspension*, and § 452.120b (formerly 148e.23) *Erythromycin ethylcarbonate for pediatric drops* and reserving them for future use.

Effective date. This order shall become effective on August 26, 1974.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357).))

Dated: July 22, 1974.

MARY A. MCENIRY,
Assistant to the Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc.74-17094 Filed 7-25-74;8:45 am]

Title 24—Housing and Urban Development

[Docket No. R-74-279]

CHAPTER II—OFFICE OF ASSISTANT SECRETARY FOR HOUSING PRODUCTION AND MORTGAGE CREDIT-FEDERAL HOUSING COMMISSIONER (FEDERAL HOUSING ADMINISTRATION), DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Interest Rate Change

The following amendments are being made to this chapter to change the maximum interest rate which may be charged on a mortgage insured by this Department from 8¾ percent to 9 percent. The Secretary has determined that such change is necessary to meet the mortgage market, in accordance with his authority contained in 12 U.S.C. 1709-1, as amended. The Secretary has, therefore, determined that advance notice and public procedure are unnecessary and that said cause exists for making this amendment effective July 8, 1974.

Accordingly, Chapter II is amended as follows:

PART 203—MUTUAL MORTGAGE INSURANCE AND INSURED HOME IMPROVEMENT LOANS

1. In § 203.20 paragraph (a) is revised to read as follows:

§ 203.20 Maximum interest rate.

(a) The mortgage shall bear interest at the rate agreed upon by the mortgagee and the mortgagor, which rate shall not exceed 9 percent per annum with respect to mortgages insured on or after July 8, 1974.

* * * * *

(Sec. 211, 52 Stat. 23; 12 U.S.C. 1715b. Interpret or apply sec. 203, 52 Stat. 10, as amended; 12 U.S.C. 1709)

2. In § 203.74 paragraph (a) is revised to read as follows:

§ 203.74 Maximum interest rate.

(a) The loan shall bear interest at the rate agreed upon by the lender and the borrower, which rate shall not exceed 9